Top Compliance and Fraud & Abuse Risk Areas for 2019

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Topics to Cover

- FY 2018 Annual Report from DHHS and DOJ
- 2019 DOJ Compliance Program Guidance
- HHS OIG Work Plan
- Federal Case Law Developments
- Stark Law
- Anti-Kickback Law
- EKRA
- Telemedicine
- HIPAA

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DHHS and DOJ Health Care Fraud and Abuse Control Program Annual Report for FY 2018

- 1139 New Criminal Health Care Fraud Investigations
- 497 Health Care Fraud Convictions
- 795 Civil Enforcement Actions
- 2,712 Exclusions
- $2.3 Billion in Settlements & Judgments
- The updated FY 2017 three year average return on investment (2015-2017) is $4.10 returned for every $1.00 expended

Compared to 2017

- **967**
- **439**
- **818**
- **3244**
- **$2.4 billion**
- **$4.20**

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U.S. Department of Justice: Evaluation of Corporate Compliance Programs

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U.S. Department of Justice: Evaluation of Corporate Compliance Programs

- Guidance Document published April 2019 (updated from 2017)

https://www.justice.gov/criminal-fraud/page/file/937501/download

- Assist prosecutors with past and present compliance program effectiveness review (Time of offense and time of charging) **Why?**
- Prosecutors should ask 3 Fundamental Questions
  - 1. Is the corporation's compliance program well designed?
  - 2. Is the program being applied earnestly and in good faith? In other words, is the program being implemented effectively?
  - 3. Does the corporation's compliance program work in practice?

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Evaluation of Corporate Compliance Programs

Design
Effective Implementation
Work in Practice

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Evaluation of Corporate Compliance Programs
Design

- Risk Assessment:
  - whether the program is appropriately "designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business" and "complex regulatory environment
  - Tailoring Resources to Risk(Appropriate attention to high risk areas, even if it fails to prevent an infraction in a low-risk area)
    - Specified high-risk areas: questionable payments to third-party consultants, suspicious trading activity, or excessive discounts to resellers and distributors

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Evaluation of Corporate Compliance Programs
Design

Policies and Procedures

- Code of conduct
- Who has been involved in the design? Which business units?
- How has the company communicated these to employees?
- Gatekeepers: Special training to those who are in a control position.

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Evaluation of Corporate Compliance Programs
Design

Training and Communication

- Periodic training and certification to directors, officers, relevant employees, agents/business partners
- Training that is appropriately tailored
- How is training effectiveness measured?
- Does training cover past compliance incidents?

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Evaluation of Corporate Compliance Programs
Design

Mergers and Acquisitions

- Comprehensive due diligence of acquisition targets
- The extent to which it conducts this due diligence is indicative of whether its compliance program is effective.
- Integrating compliance into the M & A process
- Has the company implemented compliance policies and procedures at new entities?

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Evaluation of Corporate Compliance Programs Effective Implementation

- Is it a "paper program" or one "implemented, reviewed, and revised, as appropriate, in an effective manner"?
- Appropriate staff
- Adequate Communication
- Commitment by senior management
- Incentives and Disincentives

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Evaluation of Corporate Compliance Programs Work in Practice

- whether and how the misconduct was detected, what investigation resources were in place to investigate suspected misconduct, and the nature and thoroughness of the company's remedial efforts
- Root cause analysis
- Remediation
- Revisions in light of lessons learned

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RJW1

Risk Assessment

Training and Communication

Next Steps? Review your Program And Measure Effectiveness

Appropriate Resources

Addressing Misconduct

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HHS OIG Work Plan

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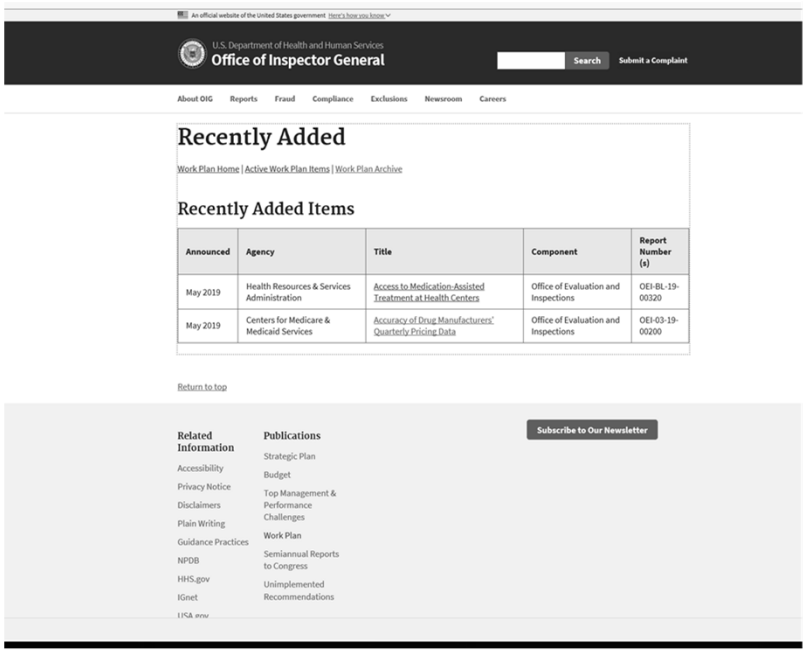

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Slide 13

RJW1 Rose J. Willis, 6/15/2019

HHS OIG Work Plan

Targeting Certain Hospitals

- CMS will determine how inpatient hospital billing has changed over time and describe how inpatient billing varied among hospitals
- CMS will use the results to target certain hospitals or codes for a medical review to determine the extent to which hospitals billed incorrect codes

Review of Monthly ESRD-Related Visits Billed by Physicians or Other Qualified Healthcare Professionals

- Approximately one-third of the payments for ESRD-related services were improper payments due to insufficient documentation, incorrect coding, or no documentation submitted
- We will review whether physicians or other qualified healthcare professionals billed monthly ESRD-related visits in accordance with Federal requirements

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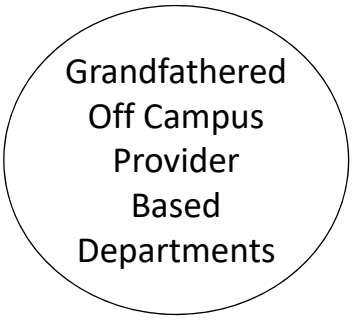
AHA Complaint and Lawsuits Against HHS

- Final Rule effective 1/1/19: Payment rate for hospital outpatient clinics provided at an excepted off-campus provider based department will be reduced to a Physician Fee Schedule equivalent rate, rather than staying at the OPPS rate.
- Excepted (grandfathered) PBDs vs. Non-excepted PBDs
- Issue: Did CMS overstep its authority when it finalized this rule?
- AHA v. Azar
- University of Kansas Hospital, et.al. v. Azar



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Federal Case Law Developments Case Study

Pursuit of Private Equity Firm for Kickbacks

United States ex rel. Medrano v. Diabetic Care RX, LLC, 2018 U.S. Dist. LEXIS 204225 (S.D. Fla. Nov. 30, 2018)

Defendants:

Pharmacy in Florida which received over $72 million in reimbursements from TRICARE for compounded drug claims over a 7-8 month period

PE Firm out of California which manages the PE fund that owns controlling stake in the Pharmacy (and managed it)

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Federal Case Law Developments Case Study

Background

- In 2012, PE Fund purchased controlling interest in Pharmacy
- Intent to sell it in 5 years
- Shortly thereafter, drop in reimbursement rates for primary source of revenue (nutritional therapy to ESRD patients)
- In 2013, PE Fund initiated Pharmacy's entry into business of non-sterile compounding of topical creams
- "quick and dramatic payback" on its investment in the Pharmacy; 90% profit margin (per board) "Make hay while the sun shines"
- Independent contractor marketers paid fee equal to 50% of the cash amounts actually collected by [the pharmacy] from referrals to [the pharmacy] by referral sources that the Marketer develops pursuant to its services relating to prescriptions for topical compounds.
- Pharmacy regularly received prescriptions for TRICARE patients by email or fax from the marketers, rather than from the patients or prescribers.
- marketers paid telemedicine docs per "consultation." Telemedicine docs never saw the patients or physically examined the patient

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Federal Case Law Developments Case Study

"[s]ometimes, as you know, that $40 copay stops people from ordering a $6000 medication, of which $5960 is free … lol,"

Pharmacy paid the cost of the copayments owed by patients referred to by Marketer, without any verification of the patients' financial need

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Federal Case Law Developments Case Study

- Relators: Former Employees of Defendant
- Allegations: Defendants violated the False Claims Act by (1) paying illegal kickbacks to marketing companies to secure prescriptions for compounded drugs reimbursed by TRICARE and (2) offering and paying remuneration to patients to induce the patients to purchase drugs reimbursed by TRICARE by waiving or satisfying copayments that the patients were obligated to pay or by providing other remuneration.
- The FCA establishes liability to the United States for an individual who, or entity that, "knowingly presents, or **causes to be presented**, a false or fraudulent claim for payment or approval
- A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim" under the FCA

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Federal Case Law Developments

- Anti-Kickback Law: United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89 (3d Cir. 2018)
- 60 Day Medicare Advantage Overpayments Rule: UnitedHealthcare Insurance Co. v. Azar, 330 F. Supp. 3d 173 (D.D.C. 2018)

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Federal "Stark" Law Developments

- 2018 Bipartisan Budget Act signed on 2/9/2018
- Desire to reduce draconian strict liability under Stark Law and increase intent based liability under AKS
- "In writing" requirement will be satisifed by any means established by Secretary of HHS, including "contemporaneous documents evidencing the course of conduct between the parties involved"
- "signature" requirement satisfied by obtaining required signatures within 90 consecutive calendar days after the arrangement became noncompliant
- Expired leases and personal services contracts: if otherwise compliant with exception, expired arrangements will remain protected so long as on same terms and conditions

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Federal Anti Kickback Statute Developments

- BBA increased penalties for knowing or intentional violations of AKS Quadrupled fines under AKS from $25,000 to $100,000 per violation
- Doubled potential prison time from 5 to 10 years

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OIG Advisory Opinions

- Advisory Opinion 19-03 (regarding a program offered by a medical center that provides free, in-home follow-up care to eligible individuals with congestive heart failure and proposed expansion to include certain individuals with COPD).
- Advisory Opinion 19-02 (regarding a pharmaceutical manufacturer's proposal to loan, on a temporary basis, a limited- functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication)
- Advisory Opinion 19-01 ((regarding a charitable pediatric clinic's arrangement under which the clinic waives cost-sharing amounts in certain circumstances)
- Advisory Opinion 18-14 ((regarding a drug company's proposal to provide free product to hospitals for the hospitals to use exclusively to treat inpatients who have been diagnosed with one particular condition)
- Advisory Opinon 18-01(regarding the effect of your exclusion from Medicare, Medicaid, and all other Federal health care programs)

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Federal Eliminating Kickbacks in Recovery Act

- EKRA: All payors!
- Criminal penalties for offering or receiving remuneration for referrals to laboratories, recovery homes and clinical treatment facilities
- Similar, but not identical, to AKS
- Note payments to bona fide employees and independent contractors safe harbor
- Intent to apply to opioid abuse

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Telemedicine/Telehealth

- CMS will now pay separately for certain physician services furnished using communication technology (e.g. virtual check-in, evaluation of recorded video and/or images submitted by an established patient).
- Treatment of Substance Abuse/Opioid Disorder IFR
  - Per CMS- patient's home is a permissible originating site for purposes of treatment of a substance use disorder or a co-occurring mental health disorder (on or after 7/1/2019)
  - New category for opioid use disorder treatment furnished by opioid treatment programs under Part B (on and after 1/1/20)

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Telemedicine/Telehealth (cont.)

- A Compliance risk area
- Compliance with an array of federal and state rules
- Licensing
- ~ 76 percent of U.S. hospitals connect with patients and consulting practitioners at a distance through the use of video and other technology (source: AHA Annual Survey)
- Medicaid program coverage
- Limitations in Medicare program
- Privacy and Security concerns

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HIPAA

- OCR: 2018 is all-time record year for HIPAA enforcement (most breaches involving 500 or more records in any other year)
- Biggest Causes: hacking/IT incidents (43%); Unauthorized access/disclosure (39%)
- 33% involved email (phishing attacks, misdirected emails)
- 20% involved network servers
- Business Associate data breaches accounted for 42% of all stolen records

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HIPAA

- Update your risk assessment
- Know your Business Associates
- PHI in the cloud
- Ensure email and other forms of communication from your providers to patients are appropriately encrypted

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HIPAA (cont.)

- OCR provides FAQs on Patient Access and APIs: right of access related to apps designated by the individual and application programming interfaces (APIs) used by the provider's electronic health record system.
- OCR Fact Sheet on Business Associate Liability under HIPAA

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- Indiana Medical Records Service Pays $100K to settle HIPAA Breach (5/23/19)
- Tennessee Diagnostic Medical Imaging Services Company Pays $3,000,000 to Settle Breach Exposing Over 300,000 Patients' Protected Health Information - May 6, 2019
- OCR Concludes 2018 with All-Time Record Year for HIPAA Enforcement - February 7, 2019
- Cottage Health Settles Potential Violations of HIPAA Rules for $3 Million - February 7, 2019
- Colorado hospital failed to terminate former employee’s access to electronic protected health information - December 11, 2018
- Florida contractor physicians' group shares protected health information with unknown vendor without a business associate agreement - December 4, 2018
- Allergy Practice pays $125,000 to settle doctor's disclosure of patient information to a reporter - November 26, 2018

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Questions?

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